Impact of FDA Changes on Hospital Reprocessing

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Premarket submission requirements:

what they are and the process for clearance

Topics

- Classification
- 510(k) or PMA?
- Premarket Organization
- Document Review Process
- Premarket Notifications
- Premarket Approval Applications
- Exempt Devices
- Opened-but-Unused
- Single Patient Use

Classification

- May 1976 premarket process begins
- Three classes I, II, III
  - Class I: general controls
  - Class II: special controls
  - Class III: premarket approval
- ALL devices grouped by generic type into one of the three classes

510(k) or PMA?

- Class III: Submit a premarket approval application (PMA), except for those for which a 510(k) is still acceptable
- Class II: Submit a premarket notification submission (510(k)), unless it is “exempt”
- Class I: no 510(k) or PMA needed except a 510(k) for “reserved” class I devices

Premarket Organization

- Office of Device Evaluation in Rockville, Maryland
- Six divisions, each assigned specific types of devices
- Each division has branches devoted to specific types of devices

Premarket Process

- Applicant submits the PMA or 510(k) to the Document Mail Center in Rockville, Md
- Submission sent to relevant review division
- First an administrative review for “filing” or acceptance
- If OK then sent to branch evaluators
- Questions, deficiencies, issues may be identified

Premarket Process Continued

- FDA calls and/or sends a letter posing questions, if needed
- If deficient, submission may be placed on a hold status
- If not, for a PMA it proceeds to a expert panel review
- Final decision.

Premarket Notifications

- What is it?
  - Section 510(k) of law
  - Notification to FDA before commercial distribution

510(k)

- The 510(k) must demonstrate that the reprocessors device is as safe and effective as a legally marketed device for which a PMA is not needed
- The test is “substantial equivalence”
- If FDA finds the device to be equivalent then the device can be sold

510(k)

- What to compare your device to:
  - an OEM device
  - another reprocessed device that is found substantially equivalent

510(k)

- Content
  - new submission cover sheet
  - device name
  - registration number
  - class
  - labeling

510(k)

- Content
  - administrative information
    - summary or statement
    - certification for Class III
    - truthful or accuracy statement
  - comparison table
  - test data per guidance
  - declarations or statements regarding standards

510(k)

- Content Suggested
  - 2 copies
  - table of contents
  - paginated
  - tabs
  - contact name(s) and number

510(k)

- Three types of 510(k)s
  - Traditional
  - Abbreviated
  - Special
- New 510(k) needed for significant changes to marketed devices

The Premarket Approval (PMA) Process

- Class III: The most stringent regulatory category for medical devices
  - Devices for which insufficient information exists to assure safety and effectiveness solely through general or special controls.

Devices Which Need a PMA

- Not Substantially Equivalent Postamendment Devices
- Preamendment Devices

PMA vs. 510(k)

- PMA
  - Safety and Effectiveness
    - valid scientific evidence
    - risk/benefit analysis
- 510(k)
  - Substantial Equivalence

Safety and Effectiveness

- Considerations
  - Persons for Whose Use the Device is Intended
  - Conditions of Use for the Device
  - Possible Benefit to Health vs Probable Injury or Illness from Use
  - Reliability of the Device
- Reliance on Valid Scientific Evidence Only

Valid Scientific Evidence

Evidence from:

- well-controlled investigations,
- partially controlled studies,
- studies and objective trials without matched controls,
- well-documented case histories conducted by qualified experts, and
- reports of significant human experience with a marketed device

Valid Scientific Evidence Is Not:

- Random Experience
- Unsubstantiated Opinions
- Reports Lacking Sufficient Details to Permit Scientific Evaluation

Contents of Application (21 CFR 814.20)

- Applicant's Name and Address
- Signature of U.S. Representative
- Table of Contents
- Summary of Safety and Effectiveness Data
- Device Description and Manufacturing Section
- Voluntary Performance Standards

Contents of Application (Continued)

- Justification for Sole Investigator
- Bibliography and Other Relevant Information
- Samples of Device (if requested by FDA)
- Proposed Draft Labeling
- Environmental Assessment or Claim of Categorical Exclusion
- Other Information Requested by FDA or Panel

Blue Book Memos and Other Guidance

- OHIP Patient Labeling Review (#G96-3)
- Refuse to File (#P90-2 & #P94-1)
- Panel Review "Optional" (#P91-2)
- PMA (GMP) Compliance Program (#91-3)
- Device Labeling Guidance (#G91-1)

Blue Book Memos and Other Guidance (cont.)

- Expedited Review (#G89-2 & #G94-2)
- Guidance for Preparation of PMA Manufacturing Information
- PMA Manual

How to Get Further Information

- World Wide Web
  - http://www.fda.gov/cdrh/index.html
- Division of Small Manufacturers Assistance
  - 800-638-2041
  - Facts-On-Demand
    - 800-899-0381
    - 301-827-0111
- PMA Staff
  - 301-594-2186

PMA Review Phases and Associated Letters

- Filing Review
- Substantive Review
- Panel Meeting
- Decision
- Final Deliberations

- Filing/Not Filing
- Major/Minor
- Panel Status
- Approvable/Not Approvable
- Approval/Denial

Filing Procedure (21 CFR 814.42)

- Applicant Will be Notified within 45 Days in Writing of Filing Status
- 180 Day Review Period Begins on Day of Receipt of the PMA or Complete Response to Refuse to File Letter
- Informal Conference and Administrative Review for Refuse to File

Refuse to File

- Blue Book Memo
- PMA Refuse to File Checklist
- Filing Review Memo
- Filing Meeting
- Boilerplate Deficiencies

Review Procedure

- Decision Based on FDA Review, Panel Recommendation, GMP and Bioresearch Monitoring Inspections
- If Approval Order Issues = Go to Market

Review Procedure (cont.)

- Federal Register Notice of Approval Decision
  - Availability of Summary of Safety and Effectiveness Data (SSED)
  - Opportunity to Petition for Administrative Review of the Decision

Exempt Devices

- Exempt from the premarket notification procedures in subpart E of part 807 in 21 CFR
- Characteristics of the device necessary for its safe and effective performance are well established
- Not exempt from any other statutory or regulatory requirements

Opened-but-Unused

- Definition: a single-use device whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient.
- Not within the scope of Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals

Same Patient Use

- Definition: a single-use device which has been used on a patient and then reused on the same patient.
- Within the scope of the Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals

Opened-but-unused and single patient use

- Current Status
- Issues
- OEM support